JUN 1 8 2002

K021009

OctaFix Occipital Cervical Plating System
510(k) Summary

SUBMITTED BY	Spinal Concepts, Inc. 12012 Technology Blvd., Suite 100 Austin, TX 78727
ESTABLISHMENT REGISTRATION NUMBER	1649384
CONTACT PERSON	David M. Hooper, Ph.D. Manager, Regulatory and Clinical Affairs
DATE PREPARED	June 4, 2002
CLASSIFICATION NAME	Spinal Interlaminal Fracture Orthosis (888.3050/KWP) Spinal Intervertebral Body Fixation Orthosis (888.3060/KWQ)
COMMON NAME	Spinal Fixation System
PROPRIETARY NAME	OctaFix Occiptal Cervical Plating System
PREDICATE DEVICE	Synthes CerviFix System (K011969)

DEVICE DESCRIPTION

The Spinal Concepts, Inc. OctaFix Occipital Cervical Plating System consists of a single horse shoe shaped piece of alloyed titanium, resembling two rods that run axially along the cervical and upper thoracic spine and are joined by a flatter, plate-like section, that is intended for fixation to the occiput. Hooks, screws, and C-Fix™ cables are intended for fixation of the OctaFix Plate. UPB II Screws are intended for fixation to the occiput and Cannulated Side Loading Closed Screws are intended for fixation to the upper thoracic spine. The rods are to be fixed to the cervical spine through either cables or laminar hooks. Components of the OctaFix Occipital Cervical Plating System are manufactured from medical grade Ti-6Al-4V ELI titanium alloy per ASTM F-136 and may be supplied sterile or non-sterile.

INDICATIONS

The OctaFix Occipital Cervical Plating System is intended to provide stabilization to promote fusion of the cervical spine and occipito-cervico-thoracic junction (occiput-T3) for the following indications: degenerative disc disease (neck pain of discogenic origin with degeneration of the disk as confirmed by patient history and radiological studies), spondylolisthesis, spinal stenosis, fracture/dislocation, atlanto-axial fracture with instability, occipito-cervical dislocation, revision of previous cervical spine fusion surgery and tumors.

The UBP II Cancellous and Cortical Bone Screws (3.5mm and 4mm diameters; 8mm-20mm threaded lengths) are used with the OctaFix Occipital Cervical Plating System to allow for occipital fixation. These UBP II Bone Screws are limited to occipital fixation only.

The C-Fix™ Cable System is used with the OctaFix Occipital Cervical Plating System to allow for wire/cable attachment to the posterior cervical spine.

The OctaFix 4mm Cannulated Side Loading Closed Screws are limited to placement in the upper thoracic spine (T1-T3) for additional stabilization of the cervical spine for the indications specified above.

MECHANICAL TEST DATA

Mechanical testing data, collected in accordance with ASTM 1717, were collected to verify the design changes. Static and fatigue data were provided to demonstrate that the design met all functional requirements.

BASIS OF SUBSTANTIAL EQUIVALENCE

The OctaFix Occipital Cervical Plating System and the CerviFix are substantially equivalent in terms of fit, form and function. Both are made from titanium alloy, and include bone screws of occipital fixation, hooks and cables for cervical fixation and screws for thoracic fixation. Both systems are based upon a rod-plate component.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 1 8 2002

David M. Hooper, Ph.D.
Manager, Clinical and Regulatory Affairs
Spinal Concepts, Inc.
12012 Technology Blvd., Suite 100
Austin, Texas 78727

Re: K021009
Trade/Device Name: OctaFix Occipital Cervical Plating System
Regulation Number: 888.3050
Regulation Name: Spinal interlaminal fixation orthosis
Regulatory Class: II
Product Code: KWP
Dated: March 26, 2002
Received: March 28, 2002

Dear Dr. Hooper:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

for Mark N Milhern

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative,
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INIDICATIONS FOR USE STATEMENT

510(k) Number (if known): K021009

Device Name: Spinal Concepts, Inc. **OctaFix Occipital Cervical Plating System**

Indications for Use:

The OctaFix Occipital Cervical Plating System is intended to provide stabilization to promote fusion of the cervical spine and occipito-cervico-thoracic junction (occiput-T3) for the following indications: degenerative disc disease (neck pain of discogenic origin with degeneration of the disk as confirmed by patient history and radiological studies), spondylolisthesis, spinal stenosis, fracture/dislocation, atlanto-axial fracture with instability, occipito-cervical dislocation, revision of previous cervical spine fusion surgery and tumors.

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for Mark N Milhous

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K021009

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: _____ OR Over-The-Counter: _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)